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DETAILED ACTION

Status of the claims: Claims 1-35, 37-56, and 58-98 are currently pending.

Priority: This application is a 371 of PCT/EP04/13683 (12/01/2004) and claims foreign priority to EUROPEAN PATENT OFFICE (EPO) 03104484.5 (12/02/2003).

Election/Restrictions

1. Applicant previously elected Group II (claims 1-94 and 98, in part, drawn to a product where R1 is IIb). The examiner has expanded group II to include claim 95 because it is also a product claim. Applicant also elected the species (allegedly reading on claims 1, 36, 57-59, 80, and 91) of compound (110) also described in example 7 having the following structure:

The examiner expanded the examination beyond the elected species and found claim 1 to be free of the prior art. Accordingly, the previously withdrawn claims of group II were rejoined for examination.

RESPONSE TO APPLICANT REMARKS

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Claim Objections

2. Claims 1 and 36 were objected to because of the following informalities: the claim does not end with a period. Applicant has corrected the informalities. This objection is **withdrawn**.

3. Claim 91 was objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. Applicant has made appropriate corrections to the claims, therefore this objection is withdrawn.

Claim Rejections - 35 USC § 103

4. Claims 1, 36, 57-59, and 80 were rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,932,538 ("Garvey" or '538).

The examiner has considered applicant's remarks regarding the selection of carvedilol from the Garvey reference when compared to the overall teaching of the prior art and found applicant's argument persuasive. Therefore, the rejection is **withdrawn**.

Claim Rejections - 35 USC § 112

5. Claims 1, 36, and 57-58 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compounds identified as having activity, does not reasonably provide enablement for the claimed utility of the entirety of the claim scope. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

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Applicant has amended the claims to narrow the scope such that the claims more closely resemble the guidance provided in the specification. Therefore the rejection is **withdrawn**.

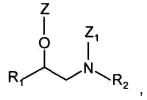
6. Claims 1 and 36 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims define a variable using terminology that one of ordinary skill in the art would not understand what constitutes the metes and bounds of the claims. Specifically, the claims use the phrase "group capable of binding Y" without providing a definition in the specification. "Binding" a variable group such as Y does not have a clear meaning in the art in this context.

Applicant has deleted the language, therefore the rejection is withdrawn.

7. Claims 1, 36, 57-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims first refer to formula (I):

$$A-(Y-ONO_2)_s$$
 (I)

then a formula (II):



however, it is not clear where the (Y-ONO2)s groups are attached on the "A" structure of formula (II).

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Applicant has amended the claim language to remove the ambiguity. This rejection is **withdrawn**.

NEW CLAIM REJECTIONS NECESSITATED BY AMENDMENT

Claim Rejections - 35 USC § 112

- 8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 9. Claims 2-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Independent claim 1 defines "s" as only 1 while the dependent claims requires "s" is only 2. This conflicting claim language would be confusing to one of skill in the art such that they would not know what applicant intends to claim.
- 10. Claims 12-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Independent claim 1 defines R1 as a particular structure while the dependent claims define R1 differently. This conflicting claim language would be confusing to one of skill in the art such that they would not know what applicant intends to claim.
- 11. Claims 26-35, and 87 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The dependent claims define Z and Z1 in a manner such that they are of a scope outside of the independent claim. This conflicting

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claim language would be confusing to one of skill in the art such that they would not know what applicant intends to claim.

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- 12. Claims 82 and 85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The dependent claims define R1 in a manner such that they are of a scope outside of the independent claim. This conflicting claim language would be confusing to one of skill in the art such that they would not know what applicant intends to claim.
- 13. Claims 37-56, 60-80, 83, 84, 86, 89, 90, 92-95, 98 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The dependent claims depend from claims that were cancelled. One of skill in the art would not know what applicant intends to claim.

Claim Objections

- 14. Claim 58 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The variable Y is of the same scope as the independent claim.
- 15. Claims 14, 17, 19, 21, 23, 25, 83, 86, 89, 90, 92-94, are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer

to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

- 16. Claims 81 is objected to because of the following informalities: the claim does not end with a period.
- 17. Claims 98 is objected to because of the following informalities: there appears to be a typographical error of a missing "a" or "one" before "pharmaceutically acceptable carrier."

Conclusion

The claims are not in condition for allowance. Any new grounds of rejection were necessitated by applicant's amendment. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT HAVLIN whose telephone number is

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(571)272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert Havlin/ Examiner, Art Unit 1626